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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/650,339 | 08/28/00 | EPSTEIN | D 0942.4630001 |

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STERNE KESSLER GOLDSTEIN & FOX PLLC
ATTORNEYS AT LAW
SUITE 600
1100 NEW YORK AVENUE NW
WASHINGTON DC 20005-3934

EXAMINER

GUTTMAN, H
ART UNIT PAPER NUMBER

1651
MAILED: 06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

| | | | |
|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 09/650,339 | Applicant(s) EPSTEIN ET AL. | |
| | Examiner Harry J Guttman | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 13, 28-30, 36, 38-43 and 48-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-12, 14-27, 31-35, 37, 44-47, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7, 8</u> . | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-55 are pending.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that (1) the groups are closely related in subject matter and are capable of use together, and (2) the burden for examination has not been established. This is not found persuasive for the following reasons. While the groups are related, the inventions are distinct as exemplified by the different classifications. Group I and Group III are different compositions (a medium vs. a medium plus a cell), and the response has not disclosed how the medium of Group I and a cell with a potentially different medium of Group III can be capable of use together. Group I and II are capable of use together since they are related as product and process of use (see page 2 of the Election/Restriction. Similarly, Group II and III are related as product and process of using, and the method of Group II can be performed using either Group I or Group III.

The different classification automatically establishes a burden to search.

It is noted that Applicant's traversal of the species elections is an admission by applicant that the species (within the genre) are obvious over one another.

The requirement is still deemed proper and is therefore made FINAL.

Art Unit: 1651

Claims 5-7, 13, 28-30, 36, 38-43 and 48-53 are withdrawn from consideration.

Claims 1-4, 8-12, 14-27, 31-35, 37, 44-47, 54 and 55 are examined on their merits insofar as they read on the elected invention and species.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Objections

Claims 9, 22 and 32 are objected to because of the following informalities: claims 9 and 22 are missing a comma after "pyridoxal", and claim 22 ends with 2 periods. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 9, 15, 22, 25, 27 and 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1651

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, **claims 4 and 27** recite the broad recitations "an acidic saccharide" and "a hydroxamate derivative", and the claims also recite "e.g., ferrous gluconate" and "e.g., acetohydroxamic acid", respectively, which are the narrower statements of the range/limitation.

Claims 2, 4, 15, 25, 27, 44, 45 and 47 contain improperly formulated markush groups because "or"s are improperly used. Correct markush language could begin with "is selected from the group consisting of:", which is followed by the list of elements and ends with a single "and" just before the last element in the list.

Claims 4, 27 and 47 recite "IRC011", "hydroxamate derivative", "porphyrin derivative", and/or "amino acid derivative". The metes and bounds for these terms have not been set forth and their meaning is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-12, 14-17, 22, 24-27, 31-35, 44-47 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Murad et al. (US 5328913).

X Murad et al. (US 5328913) disclose the inclusion of 2-hydroxypyridine-N-oxide (2HNP) and fetal calf serum with Dulbecco's modified Eagles minimum essential medium (which includes amino acids, iron(III) and chloride, and thus inherently ferric chloride) to grow fibroblasts (column 5 lines 19-68).

Claims 1-4, 11, 12, 15-17, 22, 24-27, 34, 35, 44-47 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Testa et al. (1985).

X Testa et al (1985) disclose using picolinic acid with RPMI and fetal calf serum to grow human cells (e.g., Figure 2). RPMI contains chloride and fetal calf serum contains iron.

Claims 1-4, 11, 12, 15-17, 19-27, 34, 35, 44-47, 54 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Waymouth (1984).

Art Unit: 1651

Waymouth (1984) discloses a serum-free medium containing amino acids, iron(III) and chloride (pages 49-54, and table 2) for use in growing human cells.

Waymouth discusses preparations of concentrated forms.

Claims 1-3, 11, 12, 15-26, 34, 35, 44-46 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Suhr-Jessen (WO 93/00423).

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this*

Suhr-Jessen (WO 93/00423) disclose the use citrate (an iron chelator) and FeCl_3 in a minimal medium to grow CHO and SP2/0 cells (examples 3-6)


Additional references not cited in this action have been listed in PTO-892 to establish the state of the art.

Any inquiry concerning this communication should be directed to Harry J. Guttman, Ph.D. at telephone number (703) 305-0159. The examiner can normally be reached during the hours of 07:30 to 16:00 Eastern Time, Mon.-Thurs. If attempts to reach the examiner by telephone are unsuccessful, a message may be left on the voice mail. The fax number for Art Unit 1651 is (703) 308-4242 or 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. My supervisor, Michael Wityshyn, may be contacted at (703) 308-4743.

All internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified or exchanged unless there is of record an express waiver of the confidentiality requirements of 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published in the Patent and Trademark Office Official Gazette on 25 February 1997 at 1195 OG 89.

H.J.G. 19 June 2001

Harry J. Guttman, Ph.D.
Examiner, 1651
harry.guttman@uspto.gov


SANDRA E. SAUCIER
PRIMARY EXAMINER